REMARKS

In the specification, the paragraph at page 4, line 19 has been replaced to correct grammatical errors. Claim 44 has been amended to correct minor formal inconsistencies. No new matter has been added. Entry of the amendments is respectfully requested.

The Final Office Action mailed September 1, 2005 has been received and reviewed. Claims 11-17, 20-26, and 40-50 are currently pending in the application. Applicants respectfully request reconsideration of the application herein.

35 U.S.C. § 112, First Paragraph, Claim Rejections

1. New Matter

Claims 40-50 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing new matter. The Examiner has requested that Applicants specifically point out support for new and amended claims by page and line number.

The specification refers to peptides "at least 80% identical" and "at least 90% identical" at page 17, lines 11-14; page 27, line 30 to page 28, line 12; page 96, lines 23-25; and page 97, lines 2-16. Support for survivin and HDLC1 fragments having "a contiguous span of 10 amino acids" can be found at page 96, line 28 to page 97, line 2; page 97, lines 7-16, and page 27, line 30 to page 28, line 12. Specifically, the specification at page 27, line 30 to page 28, line 12 discloses that the protein complex of the invention can be formed using survivin fragments capable of interacting with one of the survivin interactors such as HDLC1, and/or a fragment of a survivin interactor (e.g., HDLC1) capable of interacting with survivin. The specification further provides that such protein fragments can include polypeptides having a contiguous span of 10 amino acids or more of the sequence of survivin or an interactor thereof. See specification, page 96, line 28 to page 97, line 2; page 97, lines 7-16.

Applicants therefore request that the new matter rejection be withdrawn in light of support in the specification.

2. Written Description

Claims 40-50 are rejected under 35 USC §112, first paragraph, as the subject matter is allegedly not described in such a way as to reasonably convey to one of skill in the relevant art that the Applicants has possession of the invention at the time the application was filed.

In response, Applicants note several recent decisions in the Board of Patent Appeals and Interferences on nucleic acid and protein claims are illustrative. In Ex parte Rachel Meyers, Appeal No. 2003-1820, Application No. 09/464,039 (BPAI 2004), a claim at issue is drawn in part to an isolated nucleic acid molecule having "a nucleotide sequence encoding a polypeptide having dehydrogenase activity, wherein said nucleotide sequence has at least 70% sequence identity with the nucleotide sequence set forth in SEQ ID NO:8." The Board specifically reversed the Examiner's written description rejection of this claim. The Board agreed with the Applicant that "the claims are limited to nucleotide sequences meeting both the structural requirements of these claims and the claimed functional requirement – having dehydrogenase activity." Given the sequence disclosure (SEQ ID NO:8) and the Pfam tool, "a person of ordinary skill in the art at the time the invention was made would recognize the relevant structural characteristics of appellant's claimed invention that are necessary to place a polypeptide encoded by a nucleic acid variant of SEQ ID NO:8 in the dehydrogenase family of proteins."

Similarly, in Ex parte Yuejin Sun, Appeal No. 2003-1993, Application No. 09/470,526 (BPAI 2004), a claim at issue is directed in part to an isolated "wee1 polynucleotide having at least 80% identity to the coding region of SEQ ID NO:1." Rejection of the claims for lack of written description was reversed where the specification did not provide any species example of a polynucleotide other than SEQ ID NO:1. Nevertheless, the Board pointed out that the Federal Circuit has specifically instructed that "[i]n order to satisfy the written description requirement, the disclosure as originally filed does not have to provide in haec verba support for the claimed subject matter at issue." Where the specification describes (1) the polynucleotide chemical structure SEQ ID NO:1 and the structure of the polypeptide, SEQ ID NO:2, which is encoded by the SEQ ID NO:1, and (2) an example of how to screen for WEE1 activity,

the Board held that "such a description in the specification would constitute sufficiently detailed relevant identifying characteristics of the claimed subject matter consistent with Enzo."

Consistent with the Federal Circuit and the Board's decisions, the PTO's Revised Interim Written Description Guidelines Training Materials (hereinafter "Training Materials") is also instructive. For example, in Example 14 of the Training Materials, the specification discloses a single species of the claimed protein genus. "The specification also contemplates but does not exemplify variants of the protein wherein the variant can have any or all of the following: substitutions, deletions, insertions and additions. The specification indicates that procedures for making proteins with substitutions, deletions, insertions and additions is routine in the art and provides an assay for detecting the catalytic activity of the protein." USPTO Revised Interim Written Description Guidelines Training Materials, page 53 (emphasis added). The Training Material holds that the claim in Example 14, which defines a protein variant by (1) sequence identity and (2) its activity (catalytic activity), meets the written description requirement.

The Examiner has asserted that the present specification "only sets forth" the specific fragments recited in Table 1, page 21 and thus "Applicants are not in possession of essentially any and all homologues, derivatives or fragments." However, Applicants respectfully assert that the present specification meets the requirement for written description set forth by the Federal Circuit, the Board and the USPTO by disclosing a functional requirement in addition to protein sequences. Specifically, the specification teaches that claimed homologues and fragments must interact to form a survivin/HDLC1 protein complex. The specification also discloses that the survivin protein fragments having the amino acid coordinates 89-143, 3-99 and 47-143, can interact with the HDLC1 fragments having the amino acid coordinates 1-90, -20-89 and -20-89, respectively. The chemical structures of such fragments are clear in view of the GenBank references provided in the Table 1 at page 21 of the specification and the fact that the two proteins are well known in the art.

The Examiner further asserts that "structural features that could distinguish the compounds in the genus from others excluded are missing from the disclosure."

However, as discussed above, the disclosure has clearly limited the encompassed genus to protein homologues and fragments capable of forming the claimed interaction. In view of the detailed methods of determining the interaction disclosed in the specification, Applicants contend that a skilled artisan would immediately recognize and could readily determine which survivin HDLC1 fragments are encompassed by the claims. Accordingly, sufficiently detailed structural characteristics (the amino acid sequences) and the correlating functional characteristics (binding activities) are disclosed in Applicant's specification consistent with Enzo, the Board's decisions and the Training Material.

In light of the above arguments, Applicants assert that one of skill in the art would clearly recognize the polypeptides embodied by the claims. Further, the Office Action has not provided sufficient evidence to establish why one of ordinary skill in the art, provided with the descriptions in the specification discussed above, would be unable to recognize that the inventor invented and had in possession the isolated protein complex in Claims 40-50. Accordingly, the rejection should be withdrawn.

3. Enablement

Claims 40-50 stand rejected under 35 U.S.C. § 112, first paragraph, as the specification allegedly does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. Specifically, the Examiner alleges that "the specification fails to provide sufficient guidance to enable one of ordinary skill in the art to make and use the claimed polypeptides in a manner reasonably correlated with the broad scope of the claims." Applicants respectfully disagree.

The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation. United States v. Telectronics, Inc., 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988); MPEP 2164.01, 8th Edition, Rev. February 2003, p. 2100-179). The "test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question

provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed." In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) (citing In re Angstadt, 537 F.2d 489, 502-04, 190 USPQ 214, 217-19 (CCPA 1976); MPEP 2164.06, 8th Edition, Rev. 2, May 2004, p. 2100-192.

In Ex parte Yuejin Sun, the Board of Patent Appeals and Interferences reversed the Examiner's enablement rejection finding that claims drawn to a "polynucleotide having at least 80% identity to the entire coding region of SEQ ID NO:1" are enabled where the specification describes a means to test for specific biological activity of the claimed polypeptide sequence. The Examiner reasoned that "the specification does not disclose any structural or functional characteristics of any isolated nucleic acid comprising a polynucleotide having at least 80% identity to the entire coding region of SEQ ID NO.1." The Board found this reasoning unpersuasive finding that a reasonable amount of guidance to make or use a wee1 polynucleotide having 80% identity was provided by disclosure of coding sequences in combination with teachings on how to test for wee1 activity. As discussed below, Applicants respectfully assert that Claims 40-50 comport with the enablement requirements set forth by the Federal Circuit and the Board.

The Examiner first alleges that it would be "burdensome to one of skill in the art to make and use these different combinations and thereafter determine their activity" as the "disclosure has not set forth any criteria as guidance." As discussed above (See Written Description Rejection), the peptide sequences embodied by the present invention are specifically limited to those capable of interacting to form the claimed survivin/HDLC1 protein complex. Moreover, the present specification recites various methods well-known and commonly performed in the art to determine such protein-protein interactions (i.e. coimmunoprecipitation, copurification, phage display and yeast two-hybrid). See Specification, page 4, line 20 to page 6, line 15. Accordingly, one of skill in the art would not only immediately recognize, but could readily determine the sequences embodied by the claims using routine experimentation.

The Examiner's position is that "the amino acid sequence of a polypeptide determines its structural and functional properties." Applicants are not attempting to dispute this point. Rather, Applicants point out that the present application teaches

routine methods for one of skill in the art to determine which polypeptide sequences are encompassed by the present claims. Analogous to the Sun case, the specification provides extensive guidance, including working examples, to enable one of skill in the art to make and determine polypeptide sequences capable of the required interaction and, thus, embodied by the claims. For example, Specification, page 14, lines 15-24, page 29, lines 6-14; page 48, line 28 to page 49, line 6; page 57, line 23 to page 58, line 10 (examples of well-known method for determining protein-protein interactions); Specification, page 118-119 (working example); Specification, page 17, lines 16-21 (examples of orthologs and homologues, and methods of making homologues); Specification, page 17, line 22-30 (determining sequence identity).

The Examiner relies on U.S. Patent 6,168,926 to support the position that those skilled in the art recognize that high sequence identity cannot be used as a sole standard for enablement. As previously discussed, the present invention does not rely singularly on high sequence identity to enable the present claims, but further on a functional requirement requiring the proteins to interact. Applicants assert that the present invention is enabled by these requirements coupled with sufficient guidance on determining functional activity. Furthermore, Applicants believe that the patent relied upon by the Examiner actually supports enablement of the present invention by showing that survivin homologues can be readily made and are known in the art.

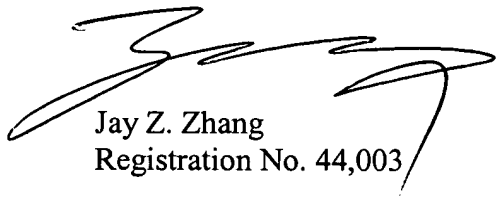
In view of the teachings of the specification and what is well-known in the art, Applicants assert that peptide sequences encompassed by Claims 40-50 can be readily determined by one of skill in the art based on their ability to interact. Thus, the present claims do not encompass "infinite possible choices" of peptide sequences as asserted by the Examiner, but rather a definite group of sequences capable of forming the claimed complex. In light of the arguments above, Applicants contend that the amount of experimentation required for one of skill in the art to determine which fragments and homologues are encompassed by the present invention is not undue. Therefore, Applicants respectfully request that the rejection of Claims 40-50 be withdrawn on this ground.

CONCLUSION

Claims 40-50 are believed to be in condition for allowance, and an early notice thereof is respectfully solicited. Should the Examiner determine that additional issues remain which might be resolved by a telephone conference, she is respectfully invited to contact Applicants' undersigned attorney.

It is not believed that any time extension or fees are required with this response. If this is incorrect, an extension of time as deemed necessary is hereby requested, and the Commissioner is hereby authorized to charge any appropriate fees or deficiency or credit any over payment to Deposit Account no. **50-1627**.

Respectfully submitted,



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